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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,291	07/12/2004	Satoshi Yonchara	10873.1449USWO	7884
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EXAMINER				
ARIANI, KADE				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,291

Applicant(s)

YONEHARA ET AL.

Examiner

KADE ARIANI

Art Unit

1651

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-11 and 13-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-11 and 13-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed on August 25, 2008, has been received and entered.

Claim 12 has been canceled.

Claims 1, 2, 4-11, and 13-30 are pending in this application and were examined on their merits.

Double Patenting Rejections

The rejection of Claims 1, 2, 4-11, and 13-30 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of Yonehara et al. US Patent No. 6,790,665, is withdrawn due to Applicants amendments to the claims filed on 08/25/2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, and 4-11, and 13-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komori et al. (European patent application, EP1 002874 A2,

Published June 24th, 2000) in view Yoshida et al. (Eur. J. Biochem., 1996, Vol. 242, 499-505) and further in view of Montellano et al. (Biochemistry, 1988, Vol. 27, pp. 5470-5476) and further in view of Ishimaru et al. (Patent number 6,127,138, Date of Patent Oct. 3, 2000), and further in view of Kwan et al. (Us patent No. 5,556,788).

Claims 1, 2, and 4-11, and 13-30 are drawn to a method of measuring an amount of a glycated protein as an analyte in a sample, comprising: causing a fructosyl amino acid oxidase (FAOD) for degradation (degradation FAOD) to the sample as a pretreatment so that a glycated amino acid as a contaminant present in the sample is degraded and removed from the sample by the degradation FAOD, adding a protease to the sample to give a degradation product of the analyte remaining in the sample, adding a fructosyl amino acid oxidase for measurement (measurement FAOD) to the sample treated with the protease to cause a redox reaction between the measurement FAPD and the degradation product of the analyte, and measuring an amount of hydrogen peroxide generated by the redox reaction to determine the amount of the analyte, wherein the redox reaction is conducted in the presence of a tetrazolium compound and sodium azide, wherein the measurement FAOD is added after the adding of the protease to the sample, wherein the measurement of the amount of hydrogen peroxide comprises adding a color-developing substrate to allow a redox reaction between the color-developing substrate and the hydrogen peroxide, and measuring an amount of color developed by the color-developing substrate to determine the amount of hydrogen peroxide further comprises, adding N-

(carboxymethylaminocarbonyl)-4,4'-bis(dimethylamino) diphenylamine sodium salt as a color-developing substrate to a reaction solution of the redox reaction in the presence of a surfactant, a concentration of the tetrazolium compound in the reaction solution is in a range from 0.5 to 8 mmol/l, a concentration of the sodium azide in the reaction solution is in a range from 0.08 to 0.8 mmol/l, a concentration of the surfactant in the reaction solution is in a range from 0.3 to 10 mmol/l, and a pH of the reaction solution is in a range from 7.0 to 8.5, the tetrazolium compound is 2-(4-iodophenyl)-3-(2,4-dinitrophenyl)-5-(2,4-disulfophenyl)-2H-tetrazolium salt, and a measuring kit for measuring a glycosylated protein.

Komori et al. teach a method of measuring an amount of a glycosylated protein as an analyte in a sample, comprising: causing a fructosyl amino acid oxidase (FAOD) to act on a glycosylated amino acid present in the sample so that the analyte remains in the sample and the glycosylated amino acid is removed from the sample by degradation; degrading the analyte with a protease to give a degradation product of the analyte either before or after causing the fructosyl amino acid oxidase to act on the glycosylated amino acid; then causing a fructosyl amino acid oxidase to act on a proteolytic degradation product of the analyte to cause a redox reaction in the presence of a tetrazolium compound and sodium azide; and measuring an amount of hydrogen peroxide generated by the redox reaction to determine the amount of the analyte, wherein the measurement of the amount of hydrogen peroxide comprises adding a color-developing substrate to allow a redox reaction between the color-developing substrate and the hydrogen peroxide (page 2, 0002-0004, and page 4 0029 and 0030). Komori et al.

teach adding a tetrazolium compound prior to the redox reaction or pretreating a sample with a tetrazolium compound to eliminate the influence of any reducing substance (Page 2 0010, and page 8 0072), and further teach the formation of hydrogen peroxide due to the oxidation of glycosylated proteins by the action of FAOD enzyme, and further teach both glycosylated peptides (proteins) and glycosylated amino acids can be subjected to the action of FAOD and glycosylated proteins and peptides are treated with a protease before its treatment with FAOD (Page 4, Lines 7-9). Komori et al. teach the color developing substrate N- (carboxymethylaminocarbonyl)-4,4'-bis(dimethylamino) diphenylamine sodium salt (DA-64) as (Page 4, Lines 3-5) and teach adding a surfactant so that its concentration in the treating solution falls in the range of 0.01- 5% by weight (Page.6 Line 5) and the concentration of tetrazolium compound (WST-3) is 1 mmol/L (Page 8, Lines 26 and 27). Komori et al. teach a peroxidase (POD) having a concentration equal to 219 KU/L (Page 17, 0095) and a reducing agent are added to the sample (Page 2, Line 12). Sigma-Aldrich catalogue discloses an active form of metalloproteinase in 10mM MES buffer, containing 0.25 mM sodium chloride and 5 mM calcium chloride and 0.01% sodium azide. Komori et al teach non-ionic surfactants such as Triton X-100 series, Tween series, Brij series and the like (page 5-6, 0044). The pretreatment is usually carried in a buffer and further recites CHES, CAPSO, CAPS, phosphate, Tris, EPPS, HEPES, pH range 8-12 (Page 6, 0047). Komori et al. teach FAOD treatment is carried out in the protease treatment solution for which a Tris-HCl, EPPS, or PIPES buffer can be used and the concentration of FAOD in the reaction solution is 50-50,000

U/L and pH of 6-9 (Page 6, 0052,0055) and 0.146 mM DA-64 (Page 17, 0095). Komori et al. also teach uricase (page7, 0066) and bilirubin oxidase (Page 7, 0064).

Komori et al. do not teach a fructosyl amino acid oxidase for degradation, a fructosyl amino acid oxidase for measurement, aging a solution containing tetrazolium compound, and sodium azide, and a measuring kit. However, Yoshida et al. teach FAODs with different substrate specificities, applicable in the enzymatic measurement of the glycated albumin, and for enzymatic measurement of glycated HbA (Introduction 2nd column 1st paragraph). Yoshida et al. teaches the amount of total glycated serum protein is known to be a more sensitive indicator of the great fluctuations in the blood glucose level generally associated with insulin-dependent diabetes. The FAOD from *P. janthinellum*, which showed higher activity toward Fru-Val, is expected to be applicable to the enzymatic determination of HbA, whose N-terminal valine residue is glycated. In this case, heme released from HbA during the reaction interferes with the coloring reaction of peroxidase in the assay (p.504 2nd column 3rd paragraph and p.505 1st column lines 1-3).

Moreover, Kwan et al. teach storing a reagent comprising tetrazolium compound by leaving the solution to stand at temperature in the range of 20-60°C for 6 to 120 hours (column 4 lines 46-48), adding sodium azide to a control reagent and incubating for 4 days at 37°C (column 6 lines 37-50). Also, Montellano et al. teach azide anion functions as an inhibitor of catalytic hemoproteins like catalase and horseradish peroxidase and using 0.15-0.6 mM sodium azide (Pg 5470 Introduction, Pg 5471, 3rd Paragraph).

Further motivation is in Ishimaru et al. who teach a method of measuring glyated protein in a sample by causing an oxidoreductase (an enzyme that catalyzes an oxidation-reduction or redox reaction) to act on glyated protein and measuring the amount of the product based on the action of the enzyme (Col.1, lines 61-66). Ishimaru et al. teach measuring a glyated protein for the purpose of the diagnosis of diabetes and further teach the method is applicable to a general-purpose examining apparatus with lower cost for a shorter period of time (Col. 2, Lines 41-44).

Therefore, in view of the above teachings, a person of ordinary skill in the art at the time the invention was made, could have been motivated to modify the method as taught by Komori et al. according to the teachings of Yoshida et al. to provide a method for measuring an amount of glyated protein in a sample with predictable results of removing the contaminant glyated amino acid. The motivation as taught by Yoshida et al. would be to provide a more sensitive enzymatic method. Moreover, a person of ordinary skill in the art at the time the invention was made, could have been motivated to use sodium azide as taught by Kwan et al. and Montellano et al. to the reagent in the method of measuring glyated hemoglobin as taught by Komori to provide a method of measuring an amount of a glyated protein as an analyte in a sample with predictable results measuring the amount of generated hydrogen peroxide. The motivation as taught by Montellano et al. would be the ability of sodium azide to inhibit the breakdown of hydrogen peroxide by the catalase that would be released into the sample as a result of hemolyzing erythrocytes and would otherwise interfere with the measurement and to prevent bacterial contamination.

Furthermore, once the method of measuring an amount of a glyated protein in an analyte was established, providing a measuring kit to determine the amount of the glyated protein would become obvious. The motivation as taught by Ishimaru et al. would be to provide a kit for the purpose of the diagnosis of diabetes.

Applicant is directed to pages 12-13 of KSR v Teleflex (500 US ____ 2007) " ... the Court has held that a "patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U. S. 147, 152 (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651